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Applicant : Carlsson et al.  
Appl. No. : 09/623,602  
Filed : 09/05/2000  
Title : TOPICAL FORMULATION OF OIL-IN-WATER TYPE  
COMPRISING OF GALACTOLIPID MATERIAL AS  
EMULSIFIER, WITH A PROLONGED EFFECT OF AN  
INCORPORATED ACTIVE SUBSTANCE

Grp./A.U. : 1616  
Examiner : Gollamudi, Sharmila S.

Docket No. : 13454NP

Honorable Assistant Commissioner of Patents  
Washington, D.C. 20231

*8/Reg for  
Recons*

*Be  
5-23-02*

Sir:

#### RESPONSE TO FINAL OFFICE ACTION

In response to the Final Office Action of February 12, 2002,  
the following is submitted:

#### REQUEST FOR RECONSIDERATION

Reconsideration is respectfully requested with respect to  
the rejection of the claims of the present application over the  
prior art cited by the Examiner for the reasons set forth below.

## THE REJECTION

Claims 1-7, 9-10 and new claim 13 have been rejected under 35 U.S.C. § 102(b) as being directly anticipated by Carlsson et al. (WO 95/20943). Claims 1-11 and claim 13 have also been rejected under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over Carlsson et al. Claims 10 and 11 have also been rejected under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over the primary reference to Carlsson et al. when considered in combination with US Patent 5,885,978 to Yamada et al.

Claim 12 has been rejected under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over the primary reference to Carlsson et al. in view of Horrobin, US Patent 4,444,755.

In the Final Office Action the Examiner has quoted from Page 5, the first paragraph of the PCT application in which it is quoted,

"An intrinsic beneficial feature of the galactolipids is the galactose units comprising the polar headgroup in each lipid molecule, which may sterically stabilise the emulsion droplets, and thus provide for a prolonged life-span when injected into the bloodstream."

In response to the Initial Office Action applicants' representatives argued that "nothing in the cited references is

stated about prolonging the effective properties of active substances." In response, the Examiner believes that applicants' representative have incorrectly stated their assumption and has referenced the first paragraph of Page 5 of the PCT application as referenced above.

Responsively, applicants' representative respectfully submits that the Examiner has not fully appreciated what is stated in the first paragraph of Page 5 of the PCT application which is the primary reference applied by the Examiner.

What is stated in the reference to Carlsson et al. is that the life-span of the emulsion droplets in the blood stream is prolonged due to the inherent properties of the galactolipid material. Thus, the droplets are preserved for a longer period of time in an aqueous medium. There is nothing in the cited reference which discusses the behavior of an incorporated active substance.

In the present invention there is a prolongation of the local effect of an active substance incorporated into a lipid carrier of an oil-in-water emulsion after application of the emulsion to the skin. In this situation, there are no emulsion droplets present as the emulsion has already broken down, and in aqueous phase, evaporated. Therefore, there is no prolongation

of the life-span of the emulsion droplets as is stated in the cited reference.

In essence, the reference does not provide any disclosure nor teaching that a pharmaceutical composition prepared in accordance with the present invention could provide a prolonged effect of a incorporated active substance when topically applied or administered.

In view of the foregoing, it is respectfully submitted that one of ordinary skill in the art would not look to the cited reference to Carlsson et al. to suggest a method of prolonging a local effect of a pharmaceutically or cosmetically active substance when such substance is used in a topical cream or lotion by providing a non-polar lipid material, an aqueous phase and a galactolipid material as emulsifier, as is taught by the present invention. What is disclosed and taught in the cited reference is that a galactolipid may sterically stabilize an emulsion droplet so as to prolong the droplets life-span when injected into a blood stream. Clearly, there is no suggestion of prolonging the effect of an active substance to be applied topically.

In view of the foregoing, it is submitted that the primary reference relied upon by the Examiner does not teach nor disclose

nor make obvious the present invention as set forth in the claims as previously amended. Therefore, withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested. Further, it is respectfully submitted that the present invention can not be anticipated nor made obvious over the cited reference, as there is no suggestion nor disclosure which would lead one of ordinary skill in the art to believe that a local effect of a pharmaceutical or cosmetically active substance could be prolonged by utilizing a galactolipid material in a formulation with such substance when applied topically, as disclosed and as claimed in the present invention.

As it is respectfully submitted that the primary reference to Carlsson et al. does not disclose, teach nor suggest a method for prolonging the effect of topical active substances as is set forth in the present invention. It is also respectfully submitted that any rejection based upon a combination including the secondary references would not be obvious.

The Examiner has maintained the rejections under 35 U.S.C. § 103(a) in that no specific argument was raised with respect to the combination of either of the secondary references to Yamada et al. or Horrobin in combination with the primary reference to Carlsson et al. Applicants respectfully request reconsideration

of the maintenance of the rejections under 35 U.S.C. § 103(a) for the combinations noted.

In responding to the Initial Office Action and as further addressed in this response, it is respectfully submitted that the primary reference does not teach any methodology for prolonging a local effect of a pharmaceutically or cosmetically active substance used in a topical cream or lotion. Therefore, even if one were to combine the teachings of the secondary references to Yamada et al. or Horrobin with the teachings of the primary reference, one would still not be lead to a methodology for prolonging the local effect of active substances as disclosed and claimed in the present application.

Yamada et al. is only cited to teach the steroidal drugs may be combined with the teachings of the reference to Carlsson et al. Such a combination does not teach prolonging a local effect of an active substance. Likewise, in the reference to Horrobin, fatty acids are disclosed for treatment of skin conditions including psoriasis. Combining the teachings of Horrobin with the primary reference to Carlsson et al. would also not teach one of ordinary skill in the art that it would be possible to prolong the local effect of an active substance utilizing an oil-in-water emulsion including an oily non-polar liquid material, an aqueous

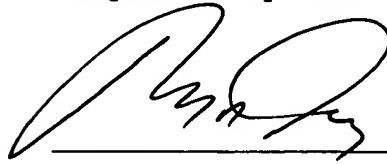
phase and a galactolipid material as an emulsifier wherein the galactolipid material is present in an amount sufficient to prolong the local effect of the active substance.

It is thus applicants position that the primary reference can not be relied upon to provide a sufficient nexus to form the basis of a combination rejection under 35 U.S.C. § 103(a) for obviousness. If the primary reference does not teach the method of the present invention nor recognize the benefits which can be obtained, as discussed above, it can not be seen how secondary references, each of which also does not teach a method for prolonging the effect of active substance can be used to reject the claims of the present application.

In view of the foregoing, reconsideration of all grounds for rejection is respectfully solicited and favorable consideration and allowance of the claims respectfully requested.

Should the Examiner have any further questions concerning the allowability of the claims over the prior art, it would be appreciated if the Examiner would schedule a personal interview with the undersigned attorney-of-record in an effort to further expedite the prosecution of this application. Absence the scheduling of a personal interview and in the event the Examiner maintains the rejection, applicant will seek an Appeal.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ralph A. Dowell', is written over a horizontal line.

Ralph A. Dowell

Registration No. 26,868

Date: January 3, 2002

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